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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,378	06/23/2003	David Farrow	SMB-004	7906

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EXAMINER	
SKOWRONEK, KARLHEINZ R	
ART UNIT	**PAPER NUMBER**
1631	

MAIL DATE	DELIVERY MODE
08/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/601,378	FARROW, DAVID	
	Examiner	Art Unit	
	Karlheinz R. Skowronek	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,8 and 22-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-8, and 22-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 1-8 and 22-29 are pending.

Claims 9-21 are cancelled.

Claims 1-8 and 22-29 are being examined.

Claim Rejections - 35 USC § 112

Response to Arguments

Applicant's arguments, see p. 6, filed 29 May 2007, with respect to the rejection of claim 7 and 8 under 35 USC112, second paragraph have been fully considered and are persuasive. The rejection of claims 7 and 8 has been withdrawn.

Claim Rejections - 35 USC § 102

Response to Arguments

Applicant's arguments, see p.8-10, filed 29 May 2007, with respect to the rejection claim 1-5 and 22 as anticipated by Ambrus have been fully considered and are persuasive. The rejection of claims 1-5 and 22 has been withdrawn.

The following rejection is reiterated from the previous office action and modified as necessitated by amendment.

Claims 1-5, 22, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Tullis et al. (American Clinical Laboratory, p.22-23, October/November 2001).

The claims are drawn to a method of detecting the presence of an analyte particle, the particle being a virus, specifically Human Immunodeficiency Virus (HIV), in a biological fluid, specifically blood. The method comprises the steps of filtering particulates that are larger than the virus, reacting the virus with a reagent to produce a complex that is larger than the virus alone, filtering the virus-reagent complex to remove particles that are smaller, and testing for the presence of the virus.

Tullis et al. teach a method of filtering HIV from blood using a filter that separates the cells (particles larger than the virus) from the HIV (p. 22, col. 1, para. 3, lines 7-10 to col. 2, line 1). Virus is passed through the filter where it complexes with a ligand reagent (antibodies) reactive to gp120 (p. 22, col. 2, lines 8-11) allow further passage of particles smaller than the viral-reagent complex particles. Tullis et al. teach the detection of Viral-reagent complexes (col.1, para. 3, lines 10-14).

Response to Arguments

Applicant's arguments filed 29 May 2007 have been fully considered but they are not persuasive. Applicant argues that the prior art does not teach the detection of the presence of reagent analyte complex. The prior art, Tullis et al. teach the detection of viral particles by PCR as captured by the reagent (p. 23, col. 1, para 3). Applicant further asserts that testing for the presence of viral RNA from viral particles captured by

the reagent does not constitute detecting reagent analyte particle complexes. This is not persuasive because the use of PCR to detect reagent analyte particle complexes does result in the detection of the presence of virus-reagent complex.

Claim Rejections - 35 USC § 103

Response to Arguments

Applicant's arguments, see p. 13-14, filed 29 May 2007, with respect to the rejection of claim 1-5, 7, and 22-25 as obvious over King et al. in view of Coller et al. have been fully considered and are persuasive. The rejection of claims 1-5, 7, and 22-25 has been withdrawn.

Applicant's arguments, see p. 14-15, filed 29 May 2007, with respect to the rejection of claim 8 as obvious over King et al. in view of Coller et al. and in further view of Peterson have been fully considered and are persuasive. The rejection of claim 8 has been withdrawn.

Applicant's arguments, see p. 15-17, filed 29 May 2007, with respect to the rejection(s) of claim(s) 1-5, 7, 8, and 22-25 as obvious over Hanna et al. in view of Bernhardt et al. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made.

Claims 1-5, 7, 8, and 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tullis et al. in view of Bernhardt et al. and in view of Peterson et al.

The claims are drawn to a method of detecting the presence of an analyte particle, the particle being a virus, specifically Human Immunodeficiency Virus (HIV), in a biological fluid, specifically blood. The method comprises the steps of filtering particulates that are larger than the virus, reacting the virus with a reagent to produce a complex that is larger than the virus alone, filtering the virus-reagent complex to remove particles that are smaller, and testing for the presence of the virus. In some embodiments, the reagents is truncated CD4. In some embodiments, filtering is done using injection molded plastic.

Tullis et al. teach a method of filtering HIV from blood using a filter that separates the cells (particles larger than the virus) from the HIV (p. 22, col. 1, para. 3, lines 7-10 to col. 2, line 1). Virus is passed through the filter were it complexes with a ligand reagent (antibodies) reactive to gp120 (p. 22, col. 2, lines 8-11) allow further passage of particles smaller than the viral-reagent complex particles. Tullis et al. teach the detection of Viral-reagent complexes by PCR (col.1, para. 3, lines 10-14).

Tullis et al. does not show Injection molded plastic and a CD4 reagent.

Bernhardt et al. teach the formation of virus-ligand complexes composed of CD4 receptor-HIV (table 1) to result in an increased particle size (col. 2, lines 10-18). The fluid containing the virus-reagent complex is subjected to ultrafiltration thereby allowing particle smaller than the virus-reagent complex to flow through the filter (col. 2, lines 20-29). Berhardt et al. show that the method will increase the safety of plasma proteins

produced from human plasma for therapy and prophylaxis and will allow for an increased rate of filtration (col. 1, line 10-33).

Peterson et al. show an injection molded plastic filtration device ([0011] and p. 9, claim 1). Peterson et al. teach the device has a solid support for capturing a desired analyte ([0050]). Peterson et al. show that the device has the superior blend of advantages of efficiency and convenience in design manufacture and use ([0010]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the filter device of Tullis with the CD4 reagent of Bernhardt et al. because the binding of HIV to antibodies or to the CD4 protein are functionally equivalent. Berhardt et al. show in table 1 that antibodies and CD4 are both suitable reagents for forming a reagent-HIV complex that may be retained during filtration of particle that are smaller than the reagent-virus complex. Berhardt et al. further motivate one of skill in the art to modify the filter of Tullis et al. because Berhardt et al. show that the method will increase the safety of plasma proteins produced from human plasma for therapy and prophylaxis and will allow for an increased rate of filtration. It would have been further obvious to modify the filter device of Tullis and the CD4 reagent of Bernhardt et al. with the injection molded plastic filtering device of Peterson et al. because Peterson et al. show that the device has the superior blend of advantages of efficiency and convenience in design manufacture and use.

The following rejection is newly applied.

Claims 1-5, 7, 8, and 22-29 rejected under 35 U.S.C. 103(a) as being unpatentable over Chou et al. (US PGPUB 2004/0072278) in view of Bernhardt et al. (US Pat 6,391,657).

The claims are drawn to a method of detecting the presence of an analyte particle, the particle being a virus, specifically Human Immunodeficiency Virus (HIV), in a biological fluid, specifically blood. The method comprises the steps of filtering particulates that are larger than the virus, reacting the virus with a reagent to produce a complex that is larger than the virus alone, filtering the virus-reagent complex to remove particles that are smaller, and testing for the presence of the virus. In some embodiments, the reagents is truncated CD4. In some embodiments, filtering is done using injection molded plastic.

Chou et al. show a microfluidics particle analysis system. Chou show that viruses are manipulated and analyzed as particles with the microfluidics system ([0167]). Chou et al. show the microfluidics device has size selective channels that filter particles based on size ([0214]). In an embodiment, Chou et al. show that blood is filtered with the device ([0460 and 0461]). Chou et al. show that the device may be configured to have cascaded size selective combs that particles of different sizes are selected ([0468]). This reads on the limitation of the instantly claim invention of filtering out particle larger than the virus and smaller than the virus. Chou et al. teach that the input fluid may be composed of particle of heterogeneous sizes and that device has a size selective retention chambers ([0461]). Chou et al. show the device is fabricated plastic through the use of a mold ([0127 and 0132]). In example 15, Chou et al. show that the

microfluidics system is used as a diagnostic tool for analyzing heterogeneous populations of particles based on differences in size ([0655]). In that example, blood is introduced into the device where particles of the fluid are separated and differentiated on the basis of size. Chou teach that larger particles are retained where smaller particles pass through the size selective barrier ([0660]). Chou teach in that example that the particles are treated by exposure to a reagent ([0661]). Chou et al teach the detection of reagent particle complexes. Chou et al. teach the microfluidics system has the advantages of improved speed, accuracy, safety, and cost ([0658]). Chou et al. teach that the CD4 receptor is the primary receptor for the human immunodeficiency virus (HIV) ([0701]).

Chou et al. do not show the formation reagent-particle complex that is separated from particles smaller than the complex.

Bernhardt et al. teach the formation of virus-ligand complexes composed of CD4 receptor-HIV (table 1) to result in an increased particle size (col. 2, lines 10-18). The fluid containing the virus-reagent complex is subjected to ultrafiltration thereby allowing particle smaller than the virus-reagent complex to flow through the filter (col. 2, lines 20-29). Berhardt et al. show that the method will increase the safety of plasma proteins produced from human plasma for therapy and prophylaxis and will allow for an increased rate of filtration (col. 1, line 10-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the differential microfluidics particle filtering system of Chou et al. with the formation of CD4-HIV complexes for the purpose of increasing the

HIV particle size of Bernhardt et al. because Bernhardt et al. show that by forming a reagent-particle complex increased filtration rates can be obtained. It would have been further obvious to use CD4 as the HIV complexing reagent because Chou et al. teach that CD4 is the primary receptor for HIV. It would also have been further obvious to modify the filtration device of Bernhardt et al. with the microfluidics system of Chou et al. because Chou et al. teach the microfluidics system has the advantages of improved speed, accuracy, safety, and cost.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is (571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

7 August 2007

/KRS/
Karlheinz R. Skowronek
Assistant Examiner, Art Unit 1631

8 August 2007

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER